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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,081	12/28/2001	Colin Chong	047711-0284	1999

7590 12/15/2004

Irvin C. Harrington, III
FOLEY & LARDNER
35th Floor
2029 Century Park East
Los Angeles, CA 90067-3021

EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,081

Applicant(s)

CHONG ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-24,44,47-53 and 55-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-24,44,47-53 and 55-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-3, 8-10, 13-17, 19, 20, 22, 44, 47-50, 53, 55-62, 65-69, 71 and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Sherry, 6,358,238.

As to claims 1, 8, 9, 10, 13, 19, 48-50, 53, 55, 60-62, 65, 71, Sherry discloses a multi-layer catheter having a first and second layer, wherein the first or second material (i.e., outer layer, or alternatively inner layer) has a permeability lower than polyethylene for CO₂ or phenolic compounds (col. 5, lines 18-19, and 21-22.) PTFE, i.e., polytetrafluorethylene, and nylon are disclosed and claimed by Applicant as having a permeability lower than polyethylene for CO₂ and phenolic compounds.

As to claims 2, 3, 56, 57, Applicant claims that the second material has a permeability lower than polyethylene for CO₂ or phenolic compounds, and Applicant claims two different embodiments, wherein one embodiment has the second material on the outside and another embodiment wherein the second material is on the inside. However, both claimed embodiments are anticipated by Sherry since Sherry discloses

that both the first and second material comprises a material that has a permeability lower than polyethylene for CO₂ and phenolic compounds.

As to claims 14, 66, the inner surface of the first material substantially covers an outer surface of the second material (see fig. 2)

As to claims 15, 16, 67 and 68, the disclosed reinforcement structure (22) at the distal tip in column 5, lines 16-21, is considered the first material, and the second material is the inner layer of PTFE.

As to claims 17, 69, an interior layer (i.e., the interior layer of the first material) contacts an inner surface of the second material, the interior layer comprising a substance that is considered to be capable of regulating an interaction of substances with the interior layer.

As to claim 20, the inner diameter of the distal end has a flared shape (see conical distal tip in fig. 2.)

As to claims 22, 44, 47 and 72, an infusion pump (syringe) is disclosed at column 4, line 38. The syringe is considered to have a sensing device (means for pumping) for regulating the delivery of a formulation.

As to claim 58, polytetrafluorethylene and nylon forming the first and second materials are capable of preventing obstructions from forming in a formulation, wherein the obstructions occur as a result of diffusion of the phenolic compounds out of the catheter.

As to claim 59, polytetrafluorethylene and nylon has a permeability lower phenolic compounds, including phenol and m-cresol.

2. Claims 1, 3-5, 11-14, 17, 19, 22, 23, 24, 44, 47, 51-53, 55, 56, 58, 59, 63-66, 69 and 71-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Barry et al., 6,663,606.

Barry discloses a multi-layer catheter (col. 5, line 5) having a first and second layer, wherein the first or second material (glass or diamond coating) has a permeability lower than polyethylene for CO₂ or phenolic compounds (col. 7, lines 20 and 24.) Glass and diamond coatings are disclosed and claimed by Applicant as having a permeability lower than polyethylene for CO₂ and phenolic compounds. An infusion pump is disclosed at column 5, line 30. As to claims 23 and 73, the first material is plastic lumen disclosed in column 9, line 46. As to claim 47, a sensing device for regulating the delivery of formulation is the pumping means of syringe (col. 9, line 46.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 18 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherry, 6,358,238, in view of Bardsley et al., 6,004,310.

Sherry discloses the invention substantially as claimed (see above), except for the interior layer contacting an inner surface of the second material, wherein the interior layer comprises a substance that is hydrophilic. Bardsley teaches a hydrophilic coating on the inside of a catheter lumen in order to improve frictional properties between a guidewire and the lumen of the catheter (col. 8, line 66 – col. 9, line 6.) It would have been obvious to one of ordinary skill in the art to provide a hydrophilic coating as taught by Bardsley in the Sherry lumen, such coating providing the advantage of decreasing friction between a guidewire passing through a catheter.

4. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherry, 6,358,238, in view of Nita et al., 5,916,192.

Sherry discloses the invention substantially as claimed (see above), except for an outer diameter of the distal end being constant across the flared shape of the inner diameter of the distal end. Nita discloses a catheter have such a distal tip, in order to cut or separate obstructive matter and aspirate the debris through the catheter (col. 7, lines 3-10.) It would have been obvious to one of ordinary skill in the art to provide a distal tip as taught by Nita in the Sherry multi-layer catheter, such tip providing the advantage of cutting matter to be aspirated through the catheter.

Response to Arguments

Examiner acknowledges that allowable subject matter was indicated in the previous Office action. However, upon further consideration, Examiner believes the above rejections are appropriate. Examiner apologizes for the inconvenience.

Conclusion

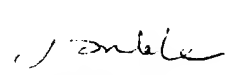
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.




LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

12/13/04